DEPARTMENT OF HEALTH & HUMAN SERVICES
New York District

Food & Drug Administration
300 Pearl Street, Suite 100
Buffalo, NY 14202

April 25, 2000

WARNING LETTER NYK 2000-67

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Dr. Douglas A. Tuthill
Noah's Ark Animal Hospital
40A Maple Avenue
Goshen, New York 13411

Dear Dr. Tuthill:

On January 14 & 18, 2000, a U.S. Food and Drug Administration investigator conducted an inspection of your veterinary clinic located in Goshen, New York. The inspection was initiated in response to three United States Department of Agriculture (USDA) reports involving illegal residues of gentamicin in cows offered for sale and slaughter for human food by [redacted]. The inspection revealed you prescribed and dispensed [redacted] containing gentamicin sulfate to [redacted] for the treatment of these cows. [redacted] subsequently offered the cows for sale for slaughter as food in violation of Section 402 (a)(2)(C)(ii) of the Federal Food, Drug and Cosmetic Act (the Act). The inspection also revealed that you caused animal drugs to become adulterated within the meaning of Section 501(a)(5).

On or about [redacted] offered a cow identified with ear tag [redacted] for slaughter as human food. The cow was later slaughtered at [redacted]. USDA analysis of tissue samples collected from that animal identified the presence of [redacted] parts per million (ppm) gentamicin. There is no permitted level for residues of gentamicin in edible tissues of cattle. The presence of this drug in kidney tissue of this animal causes the food to be adulterated within the meaning of Section 402(a)(2)(C)(ii) of the Act.

On or about [redacted] offered a cow identified with ear tag [redacted] for slaughter as human food. The cow was later slaughtered at [redacted]. USDA analysis of tissue samples collected from that animal identified the presence of [redacted] ppm gentamicin. The presence of this drug in kidney tissue of this animal causes the food to be adulterated within the meaning of Section 402(a)(2)(C)(ii) of the Act.

On or about [redacted] offered a cow identified with ear tag [redacted] for slaughter as human food. The cow was later slaughtered at [redacted]. USDA analysis of tissue samples collected from that animal identified the presence of [redacted] ppm gentamicin. The presence of this drug in kidney tissue of this animal causes the food to be adulterated within the meaning of Section 402(a)(2)(C)(ii) of the Act.

Our inspection at the [redacted] owned by [redacted] revealed that [redacted] treated the subject cows for mastitis with [redacted] without veterinary oversight. During the inspection, [redacted] stated you prescribed and dispensed the [redacted] used to treat the subject cows.

Inspection at your facility revealed you sold [redacted] seven bottles of [redacted] from January 1999 until April 1999 for use in treating dairy cattle. You stated you routinely sold the gentamicin as a component of an "XG" mixture that you promoted for the treatment of mastitis cases caused by gram-negative bacteria. The "XG" mix consists of [redacted] mls gentamicin and [redacted] mls saline and is to be administered by intramammary infusion. You gave [redacted] verbal instructions on how to prepare the mixture but you did not give him any written instructions. [redacted] stated he administered the [redacted] intramuscularly to treat his cows. He also mixed the [redacted] with dexamethasone and saline and administered the mixture as an intramammary infusion.

The [redacted] you prescribed and sold to [redacted] was adulterated under Section 501(a)(5) within the meaning of Section 512 of the Act. Section 512 deems, in part, a new animal drug is unsafe unless an FDA approved application is in effect and the drug, its labeling and use conform to such approved application. [redacted] is not approved for the treatment of cattle for any indication and is not labeled for the treatment of cattle. Therefore, use of this drug in cattle causes the drug to be adulterated.

While [redacted] is not approved for use in cattle, under certain circumstances, a veterinarian may consider such "extralabel use", as described above when the health of the animal is immediately threatened and suffering or death would result from failure to treat the affected animal. "Extralabel use" refers to the actual or intended use of a new animal drug in a food-producing animal in a manner that is not in accordance with the drug labeling. Use of gentamicin to treat mastitis in dairy cows and scours and pneumonia in calves constitutes "extralabel use".

The Animal Medicinal Drug Use and Clarification Act (AMDUCA) passed by Congress in October 1994 and the implementing regulations (Title 21 Code of Federal Regulations (CFR) Part 530) which became effective December 9, 1996, permit the extralabel use of approved human and veterinary drugs in food-producing animals only under very specific criteria as a matter of law rather than as a discretionary policy. Under AMDUCA, extralabel use must be by or on the lawful order of a licensed veterinarian within the context of a valid veterinarian/client/patient relationship and that use may not result in any residue which may present a risk to the public health. The decision to use a drug in an extralabel manner may not be made by a layperson.

When you prescribe and dispense animal drugs for extralabel use in the treatment of disease conditions in food-producing animals, you assume added responsibility. You must establish a substantially extended withholding period supported by appropriate scientific information, you must assure the identity of a treated animal is carefully maintained, and you must take appropriate measures to assure that assigned timeframes for withdrawal are met and no illegal residues occur.

The above is not intended to be an all-inclusive list of violations at your facility. It is, therefore, incumbent upon you to take added precautions such as providing detailed written and verbal instructions and cautions to all producers and animal handlers explaining the potential consequences of failing to follow your instructions. You should also limit the quantity of the drug provided, institute a method of animal identification to ensure treated animals are readily identified as such, and follow up with your clients to ensure the instructions regarding the use of the drug and prescribed withdrawal times are followed.

You should take prompt action to correct the above violations and to establish procedures whereby such violations do not recur. Failure to achieve prompt corrective action may result in regulatory action, without further notice. This may include seizure and/or injunction.

Please notify this office in writing, within 15 working days, of the steps you have taken to bring you practice into compliance with the law. Your response should include each step you have taken or will take to prevent the recurrence of similar violations. Your response should be directed to Lisa M. Utz, Compliance Officer, at the above address.

Sincerely,

Brenda J. Holman
District Director